

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

**Oral Argument Requested**

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO  
PLAINTIFFS' MOTION TO PRECLUDE OPINIONS OF DEFENSE  
LIABILITY EXPERT FENG TIAN XUE, PH.D.**

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## **INTRODUCTION**

Dr. Fengtian Xue, who was born and raised in China, earned a Ph.D. in Chemistry from Brown University and completed a postdoctoral fellowship at Northwestern University. He is a tenured professor in the Department of Pharmaceutical Sciences at the University of Maryland School of Pharmacy, where he teaches graduate-level students. Dr. Xue has published more than 85 articles, is a named inventor on 20 patents, and currently runs a research laboratory at the University of Maryland investigating therapies for cancer and other diseases. Dr. Xue has been offered to evaluate and respond to chemistry-related opinions offered by certain plaintiffs' experts, including Drs. Stephen Hecht and Ramin "Ron" Najafi. Plaintiffs' efforts to exclude his testimony are meritless.

*First*, Dr. Xue is clearly qualified to respond to plaintiffs' experts' opinions that reasonable chemists should have known about the potential for nitrosamine formation at the time valsartan API was being manufactured and sold. Plaintiffs' arguments that Dr. Xue needs highly specialized experience related to nitrosamines and FDA regulations to testify in this case is inconsistent with the law of this Circuit and his opinions.

*Second*, Dr. Xue's opinions are properly supported by his review of the same scientific literature and materials relied upon by the plaintiffs' experts to whom he is responding; his independent search of relevant literature; and his own knowledge

and experience as a professor and researcher in the field of chemistry. Plaintiffs' arguments that Dr. Xue failed to consider critical evidence and literature is meritless given that these materials were not raised by plaintiffs' own experts in their reports.

**Third**, Dr. Xue's opinions regarding the scientific meaning and import of a highly technical email addressing potential chemical reactions written in Dr. Xue's native language, and as to which plaintiffs' experts have offered their own interpretations, is proper expert testimony that will be helpful to the jury.

**Finally**, the Court should reject plaintiffs' improper suggestion that Dr. Xue's testimony will be "confusing" and "unhelpful to a jury" because he is not a native English speaker. (Pls.' Br. at 25.) Dr. Xue explained at his deposition that, because he did not move to the United States until graduate school, his spoken English "vocabulary is not the biggest" and he has a pronounced accent. (Dep. of Fengtian Xue, Ph.D. ("Xue Dep.") 15:12-17, Feb. 3, 2023 (Pls.' Br. Ex. 3).)<sup>1</sup> Dr. Xue's career as a respected professor makes clear, however, that he is more than capable of explaining issues of chemistry to a jury. Moreover, arguments that "the words [an expert] used in his deposition . . . are too confusing for the jury to understand" or that the "expert will not be eloquently spoken" are "not a basis to exclude [the

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<sup>1</sup> In addition, Dr. Xue was recovering from COVID at the time of his deposition, which made it more difficult for him to answer questions in English for many hours. (Xue Dep. 12:10-23, 25:15-26:2, 381:2-7.)

expert's] testimony.” *DPWN Holdings (USA), Inc. v. United Air Lines, Inc.*, No. 11-cv-0564 (BMC) (PK), 2019 WL 1515231, at \*10 (E.D.N.Y. Feb. 21, 2019).

For all of these reasons, plaintiffs’ motion to exclude Dr. Xue’s testimony should be denied.

### **FACTUAL BACKGROUND**

Dr. Xue began his chemistry education in his native China, where he was named “Outstanding College Student of the Year for Anhui Province (2001)” while an undergraduate at the University of Science and Technology of China. (Report of Fengtian Xue, Ph.D. (“Xue Rep.”) at 3, Dec. 22, 2022 (Pls.’ Br. Ex. 2).) He emigrated to the United States to complete his graduate-level training at Brown University, where he worked as a teaching assistant for five years, supervised more than 100 undergraduate students in general and organic chemistry labs, and earned his Ph.D. in April 2007. (*Id.*) Dr. Xue then spent two years as a postdoctoral fellow at Northwestern University, where he gained significant expertise regarding the production and reactivity of nitric oxide (NO) and its related molecules, including the nitrosonium ion (NO<sup>+</sup>),<sup>2</sup> which is a critical part of the reactions that resulted in the formulation of nitrosamines in Zhejiang Huahai Pharmaceutical Co., Ltd.’s (“ZHP’s”) valsartan active product ingredient (“API”). (*Id.* at 4.)

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<sup>2</sup> A nitrosonium ion is a nitrogen atom bonded to an oxygen atom with one electron removed.

Dr. Xue served as a tenure-track Assistant Professor in the Department of Chemistry at the University of Louisiana at Lafayette from 2009 to 2011, teaching both classroom and lab courses in Organic Chemistry. (*Id.*) During that time, he formed substantial expertise regarding what information was common knowledge in the fields of Organic and Medicinal Chemistry, and what was included in Organic Chemistry textbooks. (*Id.*)

Since 2011, Dr. Xue has run an independent research laboratory at the University of Maryland Baltimore, where he currently serves as a tenured Associate Professor in the Department of Pharmaceutical Sciences. (*Id.* at 4-5.) His lab has a broad interest in the development of small-molecule therapeutics for important human diseases, including cancer. (*Id.* at 5.) In 2022, he taught or co-taught five courses, including: Medical Chemistry 1, Organic Synthesis in Drug Design, and Principles of Drug Discovery. (*Id.*, Ex. B, at 5.)

In his expert report, Dr. Xue explains the mechanisms by which plaintiffs' experts assert that the manufacture of ZHP's API resulted in the formation of the two nitrosamines at issue in this case: N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). (*See generally id.* at 10-19.) In addition, Dr. Xue responds to chemistry-related opinions offered by plaintiffs' experts Drs. Hecht and Najafi, including opinions that ZHP conducted insufficient risk analyses and testing in connection with developing and using the "TEA with quenching" and "Zinc

Chloride” processes – and that it should have specifically looked for those nitrosamines in its valsartan API. (*See id.* at 40-43, 48-51; Report of Ramin “Ron” Najafi, Ph.D. (“10/31/22 Najafi Rep.”) at 27, Oct. 31, 2022 ([ECF No. 2292-6](#)); Report of Stephen Hecht, Ph.D. (“10/31/22 Hecht Rep.”) at 4, Oct. 31, 2022 (Pls.’ Br. Ex. 26).)

**NDEA.** Prior to April 2012, ZHP manufactured its valsartan API using a process that involved both triethylamine (“TEA”) and sodium azide. (10/31/22 Najafi Rep. at 19.) In April 2012, ZHP added a “quenching procedure . . . to guarantee [the sodium] azide” was not present in the final product. (*Id.*) According to both Drs. Hecht and Najafi, this new manufacturing process – known as TEA with quenching – resulted in the formation of NDEA. Dr. Najafi’s primary theory is that the TEA degraded into diethylamine (“DEA”), a secondary amine, and that the DEA, in turn, reacted with a nitrosonium ion ( $\text{NO}^+$ ) derived from the sodium nitrite ( $\text{NaNO}_2$ ) used in the quenching step to create NDEA. (*See id.* at 24.) This final reaction is referred to as nitrosation, because it results in a nitrosamine. Dr. Najafi asserts that it is a “well-established textbook reaction” that TEA in the presence of sodium nitrite can be nitrosated to form NDEA. (*See id.* at 27-28.) Dr. Hecht similarly states that the TEA with quenching process “led to a reaction between foreseeably created secondary amines and the nitrous acid to create NDMA/NDEA.” (10/31/22 Hecht Rep. at 1.)

As Dr. Xue explains in his report, however, Drs. Hecht and Najafi fail to identify any literature published before or during ZHP's use of the TEA with quenching process that demonstrates that TEA can react to form NDEA under the conditions present in that process. (Xue Rep. at 50.) Dr. Xue performed his own literature search and was only able to identify 10 journal articles addressing the nitrosation of TEA into NDEA (*id.*), each of which "included a special nitrosating reagent" not present in ZHP's TEA with quenching process (*id.*). Based on this analysis, Dr. Xue opined that "plaintiffs' experts have not identified any evidence that, at the time of the development of the TEA process with quenching, it was reported in the literature that TEA could react with nitrous acid (or sodium nitrite + inorganic acid) to form NDEA under the conditions present in the TEA process with quenching." (*Id.*) As a result, Dr. Xue concluded that there is no support for the proposition that "it was commonly known or expected in the field of chemistry that TEA reacts with nitrous acid (or sodium nitrite + inorganic acid) under the conditions used at ZHP to manufacture Valsartan API." (*Id.* at 50-51.)

Plaintiffs' experts were deposed after Dr. Xue submitted his rebuttal report. During the first day of Dr. Najafi's deposition, plaintiffs' counsel provided defendants with two additional articles on which Dr. Najafi purportedly relied for the proposition that it was "textbook" science that TEA could react with sodium nitrite to form NDEA (*see* Dep. of Ramin "Ron" Najafi, Ph.D. ("1/18/23 Najafi

Dep.”) 223:19-25, 224:2-7, 230:21-24, 231:8-12, 236:13-20, Jan. 18, 2023 ([ECF No. 2292-4](#))), including Zhi Sun, Yong Dong Liu, and Ru Gang Zhong, *Theoretical investigation of N-nitrosodimethylamine formation from nitrosation of trimethylamine*, Journal of Physical Chemistry A, 2010;114(1):455-465, DOI: 10.1021/jp9056219 (“Sun article”) (Pls.’ Br. Ex. 7).<sup>3</sup> Dr. Xue subsequently submitted a supplemental report in which he explained, *inter alia*, that: (1) the Sun article merely proposed a theory regarding nitrosamine formation and lacked any experimental support; and (2) the tertiary amine discussed in the article – trimethylamine – was not present in either of ZHP’s processes and it would not be reasonable for a chemist to assume that the theoretical model described in the article would apply to any other tertiary amines. (See Suppl. Report of Fengtian Xue, Ph.D. (“Xue Suppl. Rep.”) at 6-7, Jan. 30, 2023 (Pls.’ Br. Ex. 23).)

**NDMA.** In December 2013, ZHP also began manufacturing its API using a process known as the Zinc Chloride process. (10/31/22 Najafi Rep. at 24.) The Zinc Chloride process “changed the chemical reagent . . . from [TEA] to zinc chloride” and added the solvent dimethylformamide (“DMF”) to “facilitate the process.” (*Id.*)

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<sup>3</sup> Notably, on the second day of his deposition, Dr. Najafi testified that he had not read the Sun article in full and was “not relying on th[at] article for [his] opinion.” (Dep. of Ramin “Ron” Najafi Ph.D. (“1/24/23 Najafi Dep.”) 282:12-21, 283:19-25, Jan. 24, 2023 ([ECF No. 2292-12](#)).)

Both Drs. Najafi and Hecht opine in their reports that this change led to the formation of NDMA because the DMF solvent degraded during the manufacturing process into a secondary amine called dimethylamine (“DMA”), which was then nitrosated by a nitrosonium ion ( $\text{NO}^+$ ) derived from the sodium nitrite ( $\text{NaNO}_2$ ) in the quenching process to create NDMA. (See 10/31/22 Najafi Rep. at 26; Report of Stephen Hecht, Ph.D. (“7/6/21 Hecht Rep.”) at 18, 20, July 6, 2021 (Pls.’ Br. Ex. 24); 10/31/22 Hecht Rep. at 5, 7.) Dr. Najafi asserts that ZHP’s use of the “DMF solvent in the [Zinc Chloride] process should have raised concern for the possible formation of nitrosamines because DMF solvent has been long known to decompose into [DMA].” (10/31/22 Najafi Rep. at 26.) Dr. Hecht similarly claims that DMF was “well known to decompose/degrade forming” DMA. (7/6/21 Hecht Rep. at 18.)

In his responsive report, Dr. Xue explains that there is no scientific support for plaintiffs’ experts’ assertions that ZHP chemists should have known that the DMF used in the Zinc Chloride process would degrade into DMA and then react with the nitrosonium ion ( $\text{NO}^+$ ) derived from the sodium nitrite ( $\text{NaNO}_2$ ) used in the Zinc Chloride process to form NDMA. (See Xue Rep. at 40-43.) First, Dr. Xue notes that both Drs. Hecht and Najafi rely on a single Australian textbook, *Purification of Laboratory Chemicals*, Armarego, WLF (4th Edition 1996; 6th Edition 2009) (“Armarego”), for the proposition that “DMF decomposes slightly at its normal bp [boiling point] (153C) to give small amounts of dimethylamine and

CO.” (*Id.* at 41 (citations omitted).) However, “the [Zinc Chloride] process was run at a high of 135 °C, or 18 °C lower than the boiling point of DMF, and then cooled.” (*Id.*) Moreover, Dr. Xue explains, based on his own review of the literature, that “other isolated references note that ‘DMF decomposes to generate dimethylamine at >350 C,’ a significantly higher temperature.” (*Id.* (citations omitted).) Given these facts, “ZHP had no scientific reason to expect the degradation of DMF, a common solvent, under the reaction condition of 135 °C in light of the limitation in knowledge regarding this chemistry.” (*Id.*) In addition, Dr. Xue explains that although Armarego states that “DMF decomposition is catalyzed by acidic and basic materials, so that even at room temperature, DMF is appreciably decomposed if allowed to stand for several hours with solid KOH, NaOH, CaH<sub>2</sub>” (*id.* (citation omitted)), this is not relevant because in the part of the Zinc Chloride process where DMF was used, “reaction conditions were neutral.” (*Id.*) Dr. Xue also explains that a “literature search related to the synthetic method to the production of tetrazoles using [zinc chloride] as a catalyst on SciFinder generated at least 28 reports, nine of which used DMF as the solvent for the tetrazole formation reaction” and none of which “mentioned any side reaction caused by the decomposition of the DMF solvent.” (*Id.* at 42.) Thus, Dr. Xue opines that “there is no scientific support for plaintiffs’ experts’ assertions that ZHP should have expected that a secondary amine

such as [DMA] would result from the use of DMF solvent in the reaction process” and lead to the formation of NDMA. (*Id.*)

Dr. Xue also explains that, even if it had been known that DMF solvent could degrade into the secondary amine DMA, “nitrosamine formation from nitrous acid and secondary amine is a documented but rather uncommon reaction that even experienced chemists may not have learned – and was not generally known in the field of chemistry a decade ago.” (*Id.*) In responding to plaintiffs’ experts’ statement that this reaction was “basic chemistry,” Dr. Xue noted that, in his 13 years as a professor of Chemistry, he has never taught this reaction in any of his undergraduate or graduate-level courses, nor used the reaction in his own lab, where he has researched and studied potential carcinogens for the past 11 years. (*Id.* at 43.) Thus, Dr. Xue concludes that “the fact that ZHP did not specifically investigate the potential for NDMA formation [did] not render the company’s risk assessment for the [Zinc Chloride] process inadequate.” (*Id.*)

**Jinsheng Lin’s July 27, 2017 Email.** Dr. Xue’s report also responds to plaintiffs’ experts’ assertion that a highly-technical, Chinese-language email written by ZHP chemist Jinsheng Lin on July 27, 2017 demonstrates that ZHP knew in 2017 that NDMA could form during the API manufacturing process. (*See generally* Xue Rep. at 54-56.) Specifically, Dr. Xue explains that, based on his reading of the email in its original Chinese through the lens of a chemist, “[t]he email makes no reference

to possible nitrosamine formation from the TEA process with quenching or the [Zinc Chloride] process for Valsartan API.” (*Id.* at 54, 55.) Instead, Mr. Lin’s email addressed a hypothetical impurity in irbesartan, a different drug molecule than valsartan, and mentions impurity K, “a nitrosated impurity of the deacylated [v]alsartan, [and] also a different drug molecule.” (*Id.* at 55.) As part of his analysis of the email, Dr. Xue spoke to Dr. Lin, the email’s author, as well as Min Li and Jucai Ge, two of the recipients of the July 27, 2017 email, in order to understand the context in which the email was sent and both the authors’ and recipients’ understandings of whether the email referenced the formation of NDMA in connection with the manufacture of valsartan API. (*Id.* at 2.)

### **ARGUMENT**

Rule 702 has three requirements: “(1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert’s testimony must assist the trier of fact.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008). An expert opinion is reliable “if it is based on ‘good grounds,’ i.e., if it is based on the methods and procedures of science.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). The Third Circuit has emphasized that courts should not “usurp the role of the fact-finder; instead, an expert should only be excluded if ‘the flaw [in his or her methodology] is large enough that the expert lacks the “good grounds” for

his or her conclusions.” *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017) (citation omitted).

Plaintiffs’ motion to exclude Dr. Xue’s opinions fails under these standards.

**I. DR. XUE IS EMINENTLY QUALIFIED TO RESPOND TO PLAINTIFFS’ EXPERTS’ CHEMISTRY OPINIONS.**

The Third Circuit “interpret[s] Rule 702’s qualification requirement liberally.” *Pineda*, 520 F.3d at 244. Accordingly, as this Court has recognized, “[a]n expert is qualified if he ‘possesses specialized expertise.’” *Washington v. Thiele Mfg., LLC*, No. 10-685 (RBK/JS), 2012 WL 1664112, at \*7 (D.N.J. May 11, 2012) (Kugler, J.) (citations omitted). “If the expert meets [the] liberal minimum qualifications, then the level of the expert’s expertise goes to credibility and weight, not admissibility.” *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997).

Dr. Xue is a highly credentialed organic chemist who is unquestionably qualified to respond to the chemistry-related opinions offered by Drs. Hecht and Najafi, including those experts’ assertions that the reactions that caused the formation of NDMA/NDEA were “basic chemistry” of which reasonable chemists should have been aware. (*See* Xue Rep. at 43 & n.94 (responding to 10/31/22 Hecht Rep. at 7 and 10/31/22 Najafi Rep. at 7).) Indeed, Dr. Xue has taught chemistry at both the undergraduate and postgraduate levels for more than a decade and is therefore uniquely situated to assess whether the chemical reactions that led for the formation of NDMA/NDEA were “textbook” and therefore should have been

anticipated by reasonable chemists at the time ZHP's API was being manufactured and sold.<sup>4</sup> (See Xue Rep. at 4-5.) Unable to dispute Dr. Xue's qualifications as an organic chemist, plaintiffs offer illogical arguments that all of his chemistry opinions should be excluded because: (1) he did not specialize in the study of nitrosamines prior to his involvement in this case; and (2) he is not an expert in FDA regulations. Neither argument has merit.

**First**, Dr. Xue does not need specialized experience in "identifying nitrosamines" to offer his opinions. (Pls.' Br. at 5.) Third Circuit law is clear that an otherwise qualified expert need not be "an expert in the sub-specialty about which he opine[s]." *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 407 (3d Cir. 2003).

In *Schneider*, the Third Circuit reversed an order excluding the testimony of an invasive cardiologist who sought to testify about "the standard of care for **interventional** cardiologists." *Id* (emphasis added). According to the court, the expert's academic background and experience lecturing "medical students, residents and fellows in cardiology" demonstrated that he was sufficiently knowledgeable about the field of cardiology generally to offer his opinions. *Id.* at 406 n.4, 407; *see*

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<sup>4</sup> By contrast, plaintiffs' expert Dr. Najafi – who offers affirmative opinions that the reactions that led to the formation NDMA/NDEA were "textbook" and should have been anticipated by ZHP chemists – has never taught chemistry at any level. (See 10/31/22 Najafi Rep. Ex. A (Najafi CV).)

*also Pineda*, 520 F.3d at 245 (engineer with general “expertise in the stresses and other forces that might cause a material such as glass to fail” could testify about safety warnings related to glass on automobile rear liftgates despite not being a “warnings expert”).

Similarly, here, Dr. Xue’s extensive experience as a professor of chemistry qualifies him to respond to plaintiffs’ experts’ opinions regarding the mechanism by which NDMA/NDEA formed in ZHP’s API and whether ZHP chemists should have been aware of the possibility that the chemicals and reactions used in the manufacturing processes would result in NDMA/NDEA at the time they were being developed and used. This is particularly true because plaintiffs’ experts do not contend that the ZHP chemists involved in the manufacture of valsartan API had specialized training or experience in the formation of nitrosamines – but rather that information about nitrosamines was “textbook” in the field of chemistry generally. (*See* 10/31/22 Hecht Rep. at 5 (opining that “[c]hemists using processes which involve the presence of nitrite and secondary amines should absolutely be aware of” the potential for nitrosamine formation in ZHP’s processes); 10/31/22 Najafi Rep. at 27 (“process chemists working in the pharmaceutical industry” should have known about the potential for the reactions that led to the formation of nitrosamines in valsartan API because they were “well-established textbook reaction[s]”).) As a result, Dr. Xue does not need specialized qualifications to opine on what those

chemists, or other reasonable chemists, should have known or done at the relevant time based on the information available in the field.

Courts in the Third Circuit and elsewhere have repeatedly held that an expert may testify regarding what was generally known or knowable in a scientific field in which he or she has expertise. *See, e.g., Thomas & Betts Corp. v. Richards Mfg. Co.*, 342 F. App'x 754, 761 (3d Cir. 2009) (reversing exclusion of expert's testimony about "what is commonly known in the rubber molding industry" even though the expert did not specifically opine on what was known in "the subset industry of underground electrical connector manufacturing" at issue in the case); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 612 n.30 (D.N.J. 2002) (allowing expert to "testify about the state of medical knowledge concerning hematology, lymphohematopoietic disorders, leukemogenesis and chemical leukemogenesis" because the expert's "qualifications and stature as a prominent hematologist ha[d] been established"), *aff'd*, 68 F. App'x 356 (3d Cir. 2003); *Erickson v. Baxter Healthcare, Inc.*, 151 F. Supp. 2d 952, 962-63, 963-64 (N.D. Ill. 2001) (allowing epidemiologist specializing in blood-borne disease to offer opinions on "[w]hat the defendants as professional manufacturers of blood products knew or should have known and what was well known in the practicing medical community," even though he had "[n]ever been in the business of manufacturing blood products or running a blood bank").

In any event, plaintiffs are incorrect that Dr. Xue lacks experience with the science underlying the formation of nitrosamines outside of this litigation. Dr. Xue's post-doctoral work at Northwestern University involved the study of an enzyme that produces nitric oxide (NO), which "can be converted into nitrosonium ion" and is one of the "key reactant[s]" involved in the formation of nitrosamines during ZHP's manufacturing processes. (*See* Xue Rep. at 4.) As a result, Dr. Xue is more qualified to discuss what was known or should have been known about nitrosamine formation than plaintiffs' own expert, Dr. Najafi, who does not claim to have specifically studied or researched nitrosamines prior to his involvement in nitrosamine-related litigation. (*See generally* 10/31/22 Najafi Rep. and Ex. B.) Indeed, Dr. Najafi seeks to testify that the reactions that led to formation of NDEA during the TEA with quenching process were well known at the time that process was being used despite admitting that he was not aware of the possibility of those reactions prior to his involvement in this litigation. (*See* 1/18/23 Najafi Dep. 192:18-193:7; *see also id.* 193:8-15 (Dr. Najafi confirming he learned of the reaction by which TEA could form NDEA "through [his] investigation in connection with this litigation").) As a result, there is no merit to plaintiffs' assertion that Dr. Xue is unqualified to respond to plaintiffs' experts' chemistry opinions.

***Second***, Dr. Xue does not need regulatory experience to testify about issues relating to chemistry. Plaintiffs assert that Dr. Xue is not qualified to testify about

the specific “analysis that the people working at ZHP were required to conduct based on the regulations and the standard operating procedures that applied to them.” (Pls.’ Br. at 7 (citation omitted).) Dr. Xue, however, is not being offered to express any opinions about ZHP’s compliance with regulatory requirements or internal procedures. Rather, his opinions are based on a scientific analysis of whether the chemical reactions that resulted in the formation of NDEA and NDMA in valsartan API were documented in the scientific literature such that ZHP should have been aware of them at the time it was developing and using the Zinc Chloride and TEA with quenching processes. (*See* Xue Rep. at 3.) As set forth above, courts routinely allow scientific experts to offer such testimony about what was known or knowable in their field at a given time. Plaintiffs have not identified even one case suggesting that a scientist must have regulatory experience to offer such opinions.

Plaintiffs’ argument is again ironic, given that their own expert chemist, Dr. Hecht, seeks to opine that ZHP’s risk assessment was inadequate, even though he has admitted that he has no regulatory qualifications. (*See, e.g.*, Dep. of Stephen Hecht, Ph.D. 389:11-19, Aug. 17, 2021 (Ex. 1 to the Cert. of Jessica Davidson (“Davidson Cert.”)) (“Q. Doctor, you don’t hold yourself out as any sort of regulatory expert, do you, sir? A. No.”); Dep. of Stephen Hecht, Ph.D. 238:9-13, Jan. 13, 2013 ([ECF No. 2292-3](#)) (“Q. And you’ve never performed any evaluation of a manufacturer’s compliance with CGMP manufacturing practices with respect

to pharmaceuticals. Is that fair? A. Yes, correct.”).) Dr. Xue is more than qualified to respond to this assertion if it is not excluded.

For all of these reasons, plaintiffs’ qualifications arguments are baseless and should be rejected.

**II. DR. XUE’S OPINIONS REGARDING THE SCIENTIFIC ADEQUACY OF ZHP’S RISK ASSESSMENTS AND TESTING ARE BASED ON RELIABLE METHODS AND WILL ASSIST THE TRIER OF FACT.**

Plaintiffs’ arguments that Dr. Xue’s chemistry opinions are based on “subjective belief or unsupported speculation” rather than “the methods and procedures of science” (Pls.’ Br. at 6 (citation omitted)) are similarly meritless because: (1) Dr. Xue’s rebuttal of plaintiffs’ experts’ chemistry opinions is based on a reliable scientific review of the relevant evidence; and (2) none of the materials that plaintiffs claim Dr. Xue failed to properly consider are relevant to his rebuttal opinions.

**A. Dr. Xue’s Rebuttal Opinions Are Based On A Reliable Methodology.**

The Third Circuit has made clear that rebuttal opinions offered by an expert for the defendant are admissible where they are “sufficiently certain and could help the jury to evaluate testimony by plaintiff’s experts” on “an issue on which plaintiff b[ears] the burden of proof.” *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996); *see also APEX Fin. Options, LLC v. Gilbertson*, No. 19-0046-WCB-SRF, 2022 WL 613347, at \*3 (D. Del. Mar. 1, 2022) (“[A]s a rebuttal witness it [is] enough

for [an expert] to critique [the opposing party's expert's] analysis . . . ."); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007) (“[D]efendants’ experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs’ experts.”).

Notably, none of the cases cited by plaintiffs as excluding expert opinions for lack of a reliable methodology involved a rebuttal expert. Instead, plaintiffs primarily rely on cases excluding plaintiffs’ experts who failed to follow their own stated methodology in forming affirmative opinions on the issue of general causation. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 251-52 (S.D.N.Y. 2018) (Pls.’ Br. at 6, 10, 15, 16) (excluding plaintiffs’ expert who “ignore[d] scientific standards that he ha[d] conceded govern inquiries into general causation”); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 460-61, 465-66 (E.D. Pa. 2014) (Pls.’ Br. at 3, 16, 20, 25) (excluding general causation opinions offered by plaintiffs’ expert whose Bradford-Hill analysis ignored the expert’s own published studies contradicting her opinions).<sup>5</sup> Plaintiffs’ reliance on this Court’s exclusion of expert testimony in

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<sup>5</sup> The cases cited by both *In re Mirena* and *In re Zoloft* similarly involved plaintiffs’ experts who sought to offer general causation and other related opinions. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 563 (S.D.N.Y. 2004); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005).

*Player v. Motiva Enterprises LLC*, No. 02-3216(RBK), 2006 WL 166452 (D.N.J. Jan. 20, 2006) (Pls.’ Br. at 6-7, 21), is similarly misplaced. There, the Court held that the plaintiffs’ damages expert lacked a reliable basis for quantifying the diminution of value of the plaintiffs’ property following alleged contamination, a critical element of the plaintiffs’ negligence claim, because he made those calculations “without discussing, or even recognizing, the extent to which the property was actually contaminated.” *Id.* at \*7. Indeed, the expert had never “conducted any physical inspection of or visit to the properties prior to writing the report.” *Id.* Further, the expert there sought to opine on the specific percentage of property value decline without disclosing his mathematical calculations or the assumptions underlying them. *Id.* at \*8.

Dr. Xue, by contrast, is a rebuttal expert who responds directly to plaintiffs’ experts’ opinions that ZHP’s risk analyses of, and testing for API manufactured using, the TEA with quenching and Zinc Chloride processes were inadequate because ZHP failed to investigate the “straightforward” and “obvious risk” that the reactions used in those processes could result in the formation of NDEA and NDMA. (Xue Report at 19-20, *see also id.* at 40-43, 48-51.) Accordingly, Dr. Xue’s rebuttal opinions are properly based on Dr. Xue’s assessment of the same scientific literature and materials cited by plaintiffs’ experts. *See Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. 15-6480, 2021 WL 2352016, at \*15 (E.D. Pa. June 9,

2021) (defense expert’s methodology was sufficiently reliable where he had “reviewed the underlying facts and data on which [the plaintiffs’ expert] relied to reach his opinions” and had “cite[d] to econometric source materials for his opinions on principles” of economics related to his criticisms of plaintiffs’ expert).

Dr. Xue’s rebuttal opinions are also supported by his own review of the available scientific literature (*see, e.g.*, Xue Rep. at 42, 50) and his teaching experience. Courts have held that a literature review is a valid methodology upon which to base opinions about the scope of knowledge within a particular field. *See, e.g., Thomas & Betts*, 342 F. App’x at 761-62 (permitting expert to testify regarding “what is commonly known” in an industry based, in part, on a literature review); *Block v. Woo Young Med. Co.*, 937 F. Supp. 2d 1028, 1042-43 (D. Minn. 2013) (allowing medical doctor “to testify about what . . . a manufacturer would have known about the risk of pain pumps had it reviewed the literature”; “[i]t is a commonly accepted methodology to examine literature in one’s field and draw conclusions from it”). And that methodology was complemented by Dr. Xue’s substantial experience teaching both undergraduate and graduate-level chemistry courses during the relevant time period. *See, e.g., Magistrini*, 180 F. Supp. 2d at 612 n.30 (noting that in light of physician’s “qualifications and stature as a prominent hematologist,” the court would allow him to “testify about the state of medical knowledge concerning hematology, lymphohematopoietic disorders,

leukemogenesis and chemical leukemogenesis”); *Winn-Dixie*, 2021 WL 2352016, at \*15 (expert’s “background also favor[ed] finding [his] opinions reliable”).

For all of these reasons, Dr. Xue’s criticisms of plaintiffs’ experts’ opinions are based on a reliable methodology.

**B. Dr. Xue Did Not Ignore Materials Critical To His Rebuttal Opinions.**

There is also no merit to plaintiffs’ assertion that Dr. Xue’s opinions are unreliable because he did not consider: (1) whether the raw materials used in the Zinc Chloride and TEA with quenching process were contaminated with the secondary amines DMA and DEA when received by ZHP; (2) ZHP’s post-recall investigation of nitrosamine formation; and (3) a single, theoretical article addressing the potential nitrosation of tertiary amines.

*First*, none of the evidence regarding the potential contamination of raw materials identified in plaintiffs’ motion was cited in the plaintiffs’ reports to which Dr. Xue is responding. As explained in detail in defendants’ brief in support of their motion to partially exclude Drs. Hecht and Najafi ([ECF No. 2292-1](#) (“Hecht/Najafi Br.”)), neither of these plaintiffs’ experts properly disclosed an opinion that DMA and DEA were present as contaminants of the raw materials ZHP used in ZHP’s manufacturing processes or cited scientific literature or evidence to this effect. (*See generally* Hecht/Najafi Br. at 5-20.) Indeed, neither Dr. Hecht nor Dr. Najafi referenced any of the materials related to the potential contamination of raw

materials that plaintiffs assert Dr. Xue improperly failed to consider. As a result, Dr. Xue did not have a reason to rebut such opinions or evidence in his responsive report. *See generally United States v. Chrzanowski*, 502 F.2d 573, 576 (3d Cir. 1974) (“The proper function and purpose of rebuttal testimony is to explain, repel, counteract or disprove the evidence of the adverse party.”).

Nor do the documents cited in plaintiffs’ motion undermine the reliability of Dr. Xue’s opinions. For example, plaintiffs accuse Dr. Xue of failing to consider a 2001 World Health Organization report identifying DMA as a potential contaminant of DMF solution. (Pls.’ Br. at 10 (citing G. Long & M.E. Meek, *Concise International Chemical Assessment Document 31: N,N-Dimethylformamide* (WHO 2001) (“WHO Report”) (Pls.’ Br. Ex. 14)).) But, as Dr. Xue noted, the WHO Report’s statement regarding possible contaminants of DMF does not establish that those contaminants were in fact present in the DMF that ZHP purchased. (*See* Xue Dep. 128:21-129:18.) In addition, the Certificates of Analysis for DMF and TEA referenced in plaintiffs’ motion were pulled from the internet (*id.* 144:14-16, 321:6-10), and there is no evidence that those documents actually relate to any raw material used by ZHP in either its TEA with quenching or Zinc Chloride processes.<sup>6</sup>

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<sup>6</sup> Jean Juillard, *Dimethylformamide: Purification, Tests For Purity And Physical Properties*, Int’l Union of Pure and Applied Chemistry (Pergamon Press 1977) (cited in Pls.’ Br. at 14) (Pls.’ Br. Ex. 18), which was not cited by either Dr. Hecht or Dr. Najafi, also does not contradict Dr. Xue’s opinions. As plaintiffs’  
(cont’d)

In any event, the argument that an expert “did not consult certain sources that [an adversary] deem[s] relevant goes only to the weight of h[is] testimony, not its admissibility.” *Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 WL 1673805, at \*6 (E.D. Pa. May 4, 2011).

*Second*, ZHP’s Deviation Investigation Report (“DIR”) and other materials related to the company’s post-recall investigation regarding the formation of nitrosamines are not “highly relevant” to Dr. Xue’s opinions regarding what was reasonably known in the field of chemistry while ZHP was creating and using the Zinc Chloride and TEA with quenching processes. (*See* Pls.’ Br. at 15 (citation omitted).) The DIR was created in 2018, *after* the recall, to document ZHP’s investigation of how NDMA or NDEA came to be present in valsartan API. (*See* Pls.’ Br. at 16; PRINSTON00075797 (Pls.’ Br. Ex. 4).) As Dr. Xue explained at his deposition, this retrospective analysis is not relevant to what ZHP should have known about the possibility for NDMA/NDEA formation prior to the discovery of these nitrosamines in June 2018. (*See, e.g.*, Xue Dep. 113:18-114:7 (Dr. Xue explaining that ZHP “already by the year of 2018 knew that these impurit[ies] can actually form as a side product in the reaction . . . these experiment[s] [were] . . . to

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counsel notes, the article merely states that “[f]ormic acid and dimethylamine are thus predominant impurities in DMF and determine the odor of the *impure* solvent” (Xue Dep. 165:23-166:1 (emphasis added)), not that DMA is common or should be expected in all DMF.

try to figure out, as you highlight here, at different conditions how much . . . NDMA can form. I think that that’s kind of . . . backward looking back from 2018”).) The same is true with respect to litigation testimony by Dr. Min Li, a ZHP representative, acknowledging that a draft of the DIR noted *in hindsight* that ZHP had an insufficient understanding of the potential genotoxic impurities in valsartan API prior to the discovery of NDMA and NDEA in 2018. (*See* Pls.’ Br. at 23-25; Pls.’ Br. Ex. 22.) Once again, what ZHP learned in 2018 is irrelevant to Dr. Xue’s opinions about what information was available in the scientific literature years earlier, when the Zinc Chloride and TEA with quenching processes were being used.

**Third**, Dr. Xue did not “subjectively” disregard the Sun article in opining that reasonable chemists would not have known that ZHP’s processes were capable of resulting in NDMA/NDEA. (Pls.’ Br. at 19.) To the contrary, after Dr. Najafi raised the Sun article for the first time at his deposition – and then subsequently testified that he did not read the article in full and was *not* relying on it for his opinions (*see* 1/24/23 Najafi Dep. 282:12-21) – Dr. Xue submitted a supplemental report addressing the article. (*See generally* Xue Suppl. Rep. at 6-7.) Specifically, Dr. Xue explained that the Sun article: (1) is a theoretical study lacking experimental support; and (2) addressed trimethylamine, which was not used in ZHP’s processes. (*Id.*) As a result, Dr. Xue concluded that “the theoretical investigation in [the Sun article] would not have put a reasonable chemist on notice that either the TEA process with

quenching or the [Zinc Chloride] process could result in the formation of NDEA or NDMA.” (*Id.* at 7.) Dr. Xue confirmed this at his deposition. (*See, e.g.*, Xue Dep. 284:18-24 (explaining that the article was irrelevant to ZHP because it “was solely on . . . the simplest tertiary amine”); 286:5-7 (“[T]here’s no evidence from [any] experiment[s] at all to show any evidence [that] th[is] theory is correct.”).)

For all of these reasons, plaintiffs’ challenges to the methodology underlying Dr. Xue’s rebuttal opinions are baseless and should be rejected.

### **III. DR. XUE’S OPINIONS REGARDING THE JULY 27, 2017 EMAIL ARE THE PRODUCT OF RELIABLE METHODS.**

Plaintiffs are also wrong that Dr. Xue lacks a reliable basis for his opinions regarding the meaning and import of a highly technical and complex 2017 email written in Chinese by a ZHP chemist (the “July 2017 email”). (*See generally* Pls.’ Br. at 20-23; Pls.’ Br. Ex. 21, at 5-6.)

The fundamental “purpose of expert testimony is to assist the trier of facts to understand, evaluate, and decide complex evidential material.” *United States v. Perez*, 280 F.3d 318, 341 (3d Cir. 2002). Thus, the Third Circuit has “always allowed expert testimony which assists the trier of fact in understanding complex transactions that lie outside ‘the common knowledge of the average juror.’” *United States v. Chaffo*, 452 F. App’x 154, 158 (3d Cir. 2011) (citation omitted); *see also United States v. Suggs*, 230 F. App’x 175, 186 n.13 (3d Cir. 2007) (“Rule 702

permits expert testimony to assist triers of fact in understanding technical evidence.”).

The July 2017 email addresses highly technical issues related to the chemical structure of different substances and impurities outside the common understanding of the average juror. While plaintiffs’ experts contend that the email refers to a nitrosamine impurity in valsartan API, Dr. Xue explains that the email actually relates to the author’s discovery of a potential impurity in the lab-scale production of *Irbesartan*, a different drug molecule than Valsartan API, and also references impurity K, a nitrosated impurity of a third drug molecule known as deacylated Valsartan, which was described in a 2013 patent attached to the email. (Xue Rep. at 55.) As a native Chinese speaker and expert chemist, Dr. Xue is uniquely qualified to evaluate the July 2017 email and to explain why plaintiffs’ interpretation of it is inconsistent with the context of the communication as a whole.

While plaintiffs assert that Dr. Xue’s reading of the document ignores English language translations of the July 2017 email (Pls.’ Br. at 21-22), that is not the case. As Dr. Xue has explained, his opinions regarding the meaning of the email are based on this reading of the text of the July 2017 email, both in the original Chinese and in the translation relied upon by plaintiffs’ experts.<sup>7</sup> (Xue Rep. at 54-55; *see also* Xue

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<sup>7</sup> Notably, the translation of the July 2017 email that plaintiffs assert Dr. Xue should have reviewed is *not* the translation that was cited by the plaintiffs’ experts  
(*cont’d*)

Dep. 342:5-9 (Dr. Xue testifying that he read translations of the July 2017 email “along with [the] original Chinese”); *id.* 335:18-336:1 (Dr. Xue testifying that his interpretation of the email is based on his chemistry background and review of both the original and translations).) Dr. Xue opines that the entire context of the email, including the description of the chemical structure of the molecules being discussed and the attached patent, makes it clear that the email does not refer to NDMA or other nitrosamines in ZHP’s valsartan API. (Xue Rep. at 54-55.) To the extent plaintiffs or their experts disagree with Dr. Xue’s interpretation of the science set forth in the email, that is a basis for cross-examination, not exclusion. *See Lansford-Coaldale Joint Water Auth. v. Tonolli Corp.*, 4 F.3d 1209, 1216 (3d Cir. 1993) (“[I]n a battle of the experts, the factfinder ‘decide[s] the victor.’”) (quoting *Mendes-Silva v. United States*, 980 F.2d 1482, 1487 (D.C. Cir. 1993)); *United States v. UPMC*, No. 12-145, 2022 WL 2343311, at \*2 (W.D. Pa. June 29, 2022) (“[T]he [c]ourt rejects the parties’ mutual attacks on their competing expert[s]’ methodologies. These points are for a jury to decide.”).

Plaintiffs’ argument that Dr. Xue’s reading of the July 2017 email is inconsistent with testimony offered on behalf of ZHP by Min Li (Pls.’ Br. at 21) is

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to whom Dr. Xue responds and was presented to Dr. Li at his deposition. (*Compare* Pls.’ Br. Ex. 21, *with* 10/31/22 Najafi Rep. at 31 (citing Ex. ZHP-296 to Dep. of Min Li, Ph.D. (“4/20/21 Li Dep.”), Apr. 20, 2021 (Pls.’ Br. Ex. 20)), *and* 4/20/21 Li Dep. 87:19-88:7 (Pls.’ Br. Ex. 19).)

also incorrect. For one thing, Dr. Li simply agreed that plaintiffs’ counsel had correctly read the English translation of the July 27, 2017 email presented to him at this deposition. (4/20/21 Li Dep. 87:19-88:7 (“Starting at the top, it says, . . . Did I get that right? A. Yeah, yeah, it looks like.”).) In fact, Dr. Li disagreed with the assertion that the email demonstrated that “[a]s of July 27, 2017, there were people [at ZHP who knew] . . . valsartan . . . was contaminated with NDMA.” (*See* Dep. of Min Li 314:11-20, Apr. 21, 2021 (Ex. 2 to Davidson Cert.) (“No, that’s not true. As I indicated yesterday . . . based upon . . . the content . . . of that particular exhibit . . . it looks like he was [speculating].”)). In addition, plaintiffs’ assertion that “Dr. Xue admitted he was not told Min Li testified to the contents of the July 27, 2017 email” (Pls.’ Br. at 21) is a misrepresentation of Dr. Xue’s testimony. Dr. Xue made clear that he read Dr. Li’s deposition, which is cited in Dr. Xue’s report, and merely testified that he could not say whether Dr. Li’s testimony was “binding on ZHP” as a legal matter. (*See* Xue Dep. 334:3-4, 340:15-341:5.)

Finally, there is no merit to plaintiffs’ argument that Dr. Xue’s opinion is inadmissible because he conducted so-called “ex parte” interviews with ZHP employees who sent and received the July 2017 email to inform his understanding of the document. (*See* Pls.’ Br. at 22-23.) It is well established that experts can rely on out-of-court statements in forming their opinions. *See In re Paoli*, 35 F.3d at 748 (“Rule 703 permits experts to rely upon hearsay.”) (citation omitted); *Herrera v.*

*Murphy*, No. 17-4293 (SRC), 2020 WL 6787259, at \*4 (D.N.J. Nov. 18, 2020) (holding that “even if” information supporting an expert’s testimony was hearsay, the expert “may rely on such information”). Indeed, courts have held that it can be critical to interview relevant individuals whose knowledge is relevant to providing a reliable opinion. *See, e.g., Smith v. Ill. Dep’t of Transp.*, 936 F.3d 554, 558 (7th Cir. 2019) (affirming exclusion of expert that was “based on an incomplete picture” because, among other things, “she did not talk to” parties or witnesses in preparing her report); *Israel v. Smith*, No. 13-cv-0097 (PGS) (LHG), 2018 WL 1832990, at \*4 (D.N.J. Apr. 16, 2018) (excluding portion of expert’s opinion regarding how an individual’s actions would have been interpreted by witnesses where the expert did not “personally interview any of the eye-witnesses to assess their thought process”); *Viking Yacht Co. v. Composites One LLC*, 610 F. Supp. 2d 333, 337 (D.N.J. 2009) (criticizing expert who “did not conduct any research or interview any customers or marine surveyors when preparing his expert report and testimony”) (footnote omitted). Given the complex and confusing nature of the July 2017 email, and the importance placed on it by plaintiffs’ experts, Dr. Xue’s communications with the sender and some recipients of the email to understand the broader context in which it was sent bolsters, rather than undermines, the reliability of his opinions.

## **CONCLUSION**

For the foregoing reasons, the Court should deny plaintiffs' motion to exclude Dr. Xue's opinions.

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Respectfully submitted,

By: /s/ Jessica Davidson

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on April 11, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson

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